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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/113,561	08/25/1993	THOMAS R. ADAMS	DEKM:055US	3079

73905 7590 02/20/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
02/20/2008	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte
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Appeal 2007-1141
Application 08/113,561
Technology Center 1600

Decided: February 20, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 2-4 and 67, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to a fertile transgenic maize plant. Claim 67 is illustrative:

67. A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

The Examiner relies on the following prior art references to show unpatentability:

Martha A. Post-Beittenmiller et al. (Post-Beittenmiller), "Expression of Holo and Apo Forms of Spinach Acyl Carrier Protein-I in Leaves of Transgenic Tobacco Plants", 1 *The Plant Cell* 889-99 (1989).

Brian G. Fox et al. (Fox), "Stearoyl-acyl carrier protein Δ^9 desaturase from *Ricinus communis* is a diiron-oxo protein", 90 *Proc. Natl. Acad. Sci.* USA 2486-90 (1993).

Gregory Stephanopoulos et al. (Stephanopoulos), "Metabolic engineering – methodologies and future prospects", 11 *TIBTECH* 392-96 (1993).

The rejections as presented by the Examiner are as follows:

1. Claims 2-4 and 67 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

2. Claims 2-4 and 67 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

We reverse.

DISCUSSION

Claim Interpretation:

Claim 67 is drawn to a fertile transgenic maize plant. According to claim 67 the genome of the claimed transgenic maize plant has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene.

Claim 67 requires that the:

1. transgeneic maize plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise a gene encoding a grain composition trait comprising a fatty acid desaturase gene; and

2. gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

Claims 2-4 depend, directly or indirectly, from claim 67.

Written Description:

1. Claims 2-4 and 67 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

The Examiner finds that the Appellants' Specification "lists enzymes thought to be involved in fatty acid synthesis including fatty acid desaturase on page 45, lines 27-29" (Ans. 5). Specifically, Appellants' Specification discloses that

> DNA sequences may be introduced [into the plant] which slow or block steps in fatty acid biosynthesis resulting in the increase in precursor fatty acid intermediates. Genes that might by added include desaturases, epoxidases, hydratases, dehydratases, and other enzymes that catalyze reactions involving fatty acid intermediates. Representative examples of catalytic steps that might be blocked include the desaturations from stearic to oleic acid and oleic to linolenic acid resulting in the respective accumulations of stearic and oleic acids. Another example is the blockage of elongation steps resulting in the accumulation of c_8 to c_{12} saturated fatty acids.

(Spec. 45: 27 - 46: 5.)

Nevertheless, the Examiner finds that Appellants' Specification:

1. "does not provide guidance for the isolation or identification of even a single gene from a single source and of a single sequence which encodes any fatty acid desaturase" (Ans. 4);

2. fails to identify "other publications which teach genes encoding such enzymes, and does not attempt to incorporate by reference their teachings" (Ans. 5 (emphasis removed));

3. fails to establish a "relationship between structure (gene or enzyme sequence) and function (enzyme activity or phenotypic change at the whole plant level)" (*id.* (emphasis removed));

4. fails to provide a representative example of the claimed genus (*id.*);

5. that no parent of the instant application identifies "any enzyme involved in grain composition or fatty acid synthesis, or suggest maize plant transformation therewith. Accordingly, the effective filing date for maize transformed with the instantly claimed fatty acid desaturase genes is the filing date of the instant application, namely 25 August 1993" (*id.*).

Based on these findings the Examiner concludes that

> [g]iven the claim breadth and lack of guidance as discussed above, wherein the specification fails to provide any written description of even a single species (a fatty acid desaturase enzyme or gene encoding it, to be inserted into a transformed maize plant), the specification fails to provide an adequate written description of the genus as broadly claimed (maize plants transformed with the genus of sequences of any and all fatty acid desaturase enzymes and any and all genes encoding them). Accordingly, one skilled in the art would not have recognized Applicant[s] to have been in possession of the claimed invention at the time of filing.

(Ans 6.)

In response, Appellants assert that notwithstanding the Examiner's unsupported conclusions "numerous fatty acid desaturases were known and found in the literature prior to the August, 1993 filing date" (App. Br. 7). In support of this assertion Appellants direct attention to:

A. McDonough[1] which describes "a *Saccharomyces cerevisiae* OLE1 gene encoding delta-9 fatty acid desaturase, an enzyme which forms the monounsaturated palmitoleic (16:1) and oleic (18:1) fatty acids from palmitoyl (16:0) or stearoyl (18:0) CoA" (*id.*).

B. Fox which describes "a gene enxoding a stearoyl-acyl carrier protein delta 9 desaturase from castor that was expressed in *Escherichia coli*" (*id.*). According to Appellants, Fox "compared the primary structures of catalytically diverse proteins to identify conserved amino acid motifs involved in eukaryotic fatty acid desaturation" (*id.*).

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[1] Virginia M. McDonough et al. (McDonough), Specificity of Unsaturated Fatty Acid-regulated Expression of the *Saccharomyces cerevisiae OLE1* Gene, 267(9) J. Biol. Chem. 5931-36 (1992). Attached to Appellants' App. Br. as Exhibit A.

C. Reddy[2] which describes "the cloning of a delta 6-desaturase from the cyanobacteria *Synechocystis* that is responsible for the conversion of linoleic acid (18:2) to gamma-linolenic acid (18:3 gamma) (*id.*). In addition, Appellants explain that "[a] delta 12-desaturase gene linked to the delta 6-desaturase gene was also identified [in Reddy] and expression of the delta 6- and delta 12-desaturases in *Synechococcus* deficient in both desaturases carried out to result in the production of linoleic acid and gamma-linolenic acid" (*id.*).

D. Arondel[3] which describes "a gene from *Arabidopsis thaliana* that encodes an omega-3 desaturase" (App. Br. 8).

E. Thompson[4] which "describes plant Δ9 desaturases" (*id.*).

F. Browse[5] which "describes soybean and *Brassica* Δ15 desaturases" (*id.*).

G. Hitz[6] which "describes soybean stearoyl-ACP desaturases" (*id.*).

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[2] AS Reddy et al. (Reddy), Isolation of a delta 6-desaturase gene from the cyanobacterium Synechocystis sp. Strain PCC 6803 by gain-of-function expression in anabaena sp. Strain PCC7120, 22(2) Plant Mol. Biol. 293-300 (May 1993) (PubMed Abstract). Attached to Appellants' App. Br. as Exhibit C.

[3] V. Arondel et al. (Arondel), Map-based cloning of a gene controlling omega-3 fatty acid desaturation in *Arabidopsis*, 258(5086) Science 1353-55 (1992) (PubMed Abstract). Attached to Appellants' App. Br. as Exhibit D.

[4] Gregory A. Thompson et al. (Thompson), WO 91/13972, Sep. 19, 1991. Attached to Appellants' App. Br. as Exhibit E.

[5] John Browse et al. (Browse), EP 0 616 644 B1, Sep. 28, 1994. International publication number WO 93/011245, published June 10, 1993. Attached to Appellants' App. Br. as Exhibit F.

[6] William D. Hitz (Hitz), EP 0 537 178 B1, Apr. 21, 1993. Attached to Appellants' App. Br. as Exhibit G.

According to Appellants' "[t]hese examples demonstrate that genes encoding fatty acid desaturases were well known in the art" as of their August 25, 1993 filing date (App. Br. 8).

The Examiner disagrees. According to the Examiner, desaturase genes within "the broadly claimed genus of any gene of any sequence from any organism encoding any type of fatty acid desaturase protein of any sequence" were *not* well-known and publicly available prior to the filing date of Appellants' claimed invention (Ans. 8). The Examiner relies on two lines of reasoning to support of this assertion.

First, the Examiner's reasons that the references cited by Appellants "were published after the effective filing date of claims drawn to transformed maize plants in general. As the claims are drawn to transformed maize plants, these references are insufficient to prove that the instantly claimed invention was well-known in the art prior to Appellant's disclosure" (Ans. 11). This assertion misses the point. Appellants' did not rely on the references discussed above to "prove" that Appellants' invention was well-known in (e.g., obvious in view of or anticipated by) the prior art. Instead, Appellants rely on the cited references to demonstrate that those of ordinary skill in this art would have recognized that genes within the genus of fatty acid desaturase genes were known in the art as of Appellants' August 25, 1993 filing date.

Second, the Examiner directs attention to Fox in support of the argument that there is no known structure/function relationship among fatty acid desaturase proteins (Ans. 11-12).

We are not persuaded by the Examiner's reasoning on this record. The written description requirement obliges an applicant to "convey with

reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). Appellants' claimed invention is to a transgenic maize plant augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene. This claimed invention must be interpreted as it would have been understood by one of skill in the art at the time the invention was made. *Id.*; *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("the 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge"). On this record, Appellants' have demonstrated that a variety of fatty acid desaturase genes were known in the art as of their August 25, 1993 filing date.

We recognize the authority relied upon by the Examiner to support his position (Ans. 5-7 and 9-11). This authority does not, however, "establish a *per se* rule requiring nucleotide-by-nucleotide reanalysis when the structure of the component DNA segments is already known, or readily determined by known procedures". *Capon*, 418 F.3d at 1356.

It may be that the Examiner is concerned that while the evidence on this record establishes that fatty acid desaturase genes were known in the art as of Appellants' filing date, Appellants have not accounted for fatty acid desaturase genes that may have, or will, become known after Appellants' filing date. We note, however, that "[t]he law does not expect an applicant to disclose knowledge invented or developed after the filing date. Such disclosure would be impossible. *See In re Hogan*, 559 F.2d 595, 605-06

(CCPA 1977)." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). "As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." *Capon*, 418 F.3d at 1358. The preponderance of the evidence on this record supports a conclusion that a person of ordinary skill in the art would have recognized that Appellants were in possession of the claimed invention as of their filing date.

For the foregoing reasons we reverse the Examiner's rejection of claims 2-4 and 67 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

2. Claims 2-4 and 67 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

The Examiner finds that the claims

> broadly recite that the presence of the transgene confers any distinguishable phenotype on the transformed maize plants and seeds, wherein the phenotype is not specified, and may include increased disease resistance, increased cold tolerance, increased plant height, increased yield, increased insect resistance, altered carbohydrate content, increased drought tolerance, or changes in the color of flowers, fruits or leaves, etc.

(Ans. 14 (emphasis removed).) In this regard, the Examiner finds that "[t]he process of altering fatty acid composition in transformed plants . . . is unpredictable" (Ans. 15 (emphasis removed)). In support of his position the Examiner relies on Post-Beittenmiller and Stephanopoulos.

The Examiner finds that Post-Beittenmiller teaches "that transformation [of tobacco plants] with an acyl carrier protein gene failed to

produce any detectable phenotypic change in fatty acid synthesis or accumulation, even though acyl carrier protein [ACP] is involved in fatty acid biosynthesis in native [tobacco] plants (see, e.g., page 889, Abstract)" (*id.*).

The Examiner finds that Stephanopoulos teaches

> that plant transformation for the modification of fatty acid accumulation generally has not been successful, that few eukaryotic organisms have had their metabolic pathways successfully altered, and that such alteration of metabolic pathways and accumulated metabolic products is limited by lack of knowledge of the rate limiting step, the existence of multiple rate limiting steps, and the evolved resistance of metabolic pathways to change even when a single enzyme or single step is altered (see, e.g., page 392, Abstract; paragraph bridging page 392 and 393; page 393, paragraph bridging the columns; page 394, paragraph bridging the columns and the bottom two paragraphs of column 2; page 395, top paragraph; page 396, column 1, bottom paragraph).

(Ans. 15.)

Based on this evidence the Examiner concludes that it would require undue experimentation for a person of ordinary skill in this art to transform maize plants with any fatty acid desaturase gene "and to evaluate and obtain transformed maize plants with any type of altered phenotype following said transformation" (Ans. 16).

In response, Appellants assert that contrary to the Examiner's intimation, Post-Beittenmiller "'demonstrated that the levels of [transgenic spinach ACP] in tobacco chloroplasts could be raised twofold to threefold above the endogenous tobacco ACP' and this increased total ACP levels 3-4 fold " and "that 'approximately 5 to 20% of the spinach ACP-I expressed in tobacco leaves was in the C8-C18 acyl form (similar to levels detected in

spinach), providing a clear demonstration that spinach ACP-I participated in tobacco fatty acid metabolism" (Reply Br. 12 (alteration original, emphasis removed)). According to Appellants, Post-Beittenmiller's results are consistent with their claimed invention (*id.*).

Similarly, Appellants assert that Stephanopoulos teach that "some 'metabolic engineering' efforts have met with success, while the authors are also aware of other efforts that yielded 'marginal results'" (*id.*). Thus, Appellants assert that Stephanopoulos fails to support the Examiner's position as even "subjectively 'marginal' results" support their position that the claimed invention is supported by the enabling disclosure of their Specification (Reply Br. 12-13).

Further, Appellants direct attention to the Ursin Declaration[7] to demonstrate "that the expression of Δ6 and Δ15 desaturases in maize results in an alteration in the fatty acid profile of corresponding transgenic plants that renders them identifiable over the corresponding non-transgenic plants" (App. Br. 11). Appellants admit, however, that Ursin utilized a transformation technique that was not disclosed in their Specification and that the desaturase genes utilized by Ursin were unknown prior to the filing date of their application (App. Br. 11-12). Nevertheless, Appellants assert that the particular transformation technique used to transform maize is irrelevant and that the evidence of record establishes that other Δ6 and Δ15 desaturases were known in the art prior to their filing date (App. Br. 12). Accordingly, Appellants assert that the Ursin Declaration "establishes that fatty acid desaturase gene expression in maize occurs in a predictable

[7] App. Br. Exhibit H.

manner and serves to distinguish transgenic plants from corresponding non-transgenic plants" (App. Br. 12).

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999). We note, however, that "nothing more than objective enablement" is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or "illustrative examples." *In re Marzocchi*, 439 F.2d 220, 223, (CCPA 1971). As set forth in *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993):

> When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

As Appellants point out, the evidence relied upon by the Examiner fails to support his position that it would require undue experimentation to transform maize plants with a fatty acid desaturase gene to obtain transformed maize plants with an altered phenotype (*see* Ans. 16). Instead, the preponderance of the evidence on this record supports Appellants' position that it would no require undue experimentation to practice the invention as claimed.

We recognize the Examiner's arguments that "it is highly unlikely that plant transformation with fatty acid desaturase genes would cause a

multitude of phenotypes unrelated to fatty acid type or content, such as changes in flower color, plant height, etc., as encompassed by the claims" (Ans. 15). We agree, however, with Appellants that "[t]he claims do not require a 'multitude of phenotypes unrelated to fatty acid type or content.' Rather the claims require only a phenotypic change that renders the claimed transgenic maize plant identifiable over the corresponding untransformed maize plant" (Reply Br. 13).

On reflection, we find that the preponderance of the evidence on this record falls in favor of Appellants. Accordingly, we reverse the rejection of claims 2-4 and 67 under the enablement provision of 35 U.S.C. § 112, first paragraph.

CONCLUSION

In summary, we reverse the rejections of record.

REVERSED

Ssc:

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